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(54) **Catheter for even distribution of therapeutic fluids.**

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Description

BACKGROUND OF THE INVENTION

This invention generally relates to a vascular catheter for the delivery of therapeutic fluids and particularly for the uniform delivery of such fluids to an artery of a patient.

The utilization of therapeutic fluids such as those containing tissue plasminogin and activator (TPA), streptokinase, urokinase, and the like have been promising in the treatment of cardiovascular diseases. The systemic use of such therapeutic fluids has been limited by the fact that the total body is medicated in order to effect sites in the coronary anatomy. Delivery of such therapeutic fluids directly to the target tissue would allow a much more effective treatment procedure but to date, there have been no effective delivery systems available. Moreover, there are no delivery systems which can deliver a uniform quantity of therapeutic fluids to a cardiovascular region, particularly at the low volume rates believed to be needed. The present invention provides such a system.

EP-A-0 378 178 is the closest but not prepublished state of the art (Art. 54(3)(4)EPC).

SUMMARY OF THE INVENTION

The present invention is directed to a vascular catheter which provides for a more effective uniform delivery of therapeutic fluids to a desired location within a patient's vasculature.

The vascular catheter in accordance with the present invention provides a multilumen catheter for delivery of therapeutic fluid to a location within a patient's vascular system, comprising an elongated tubular body having a first lumen with an axial opening in the distal end of the tubular body which is adapted to receive a guidewire and at least one additional lumen which is adapted to receive therapeutic fluid, a plurality of longitudinally spaced fluid passageways which extend through a sidewall of the elongated tubular body from an inner lumen adapted to receive therapeutic fluid to the exterior of the tubular body, the transverse cross-sectional area of the passageways and the spacing therebetween being varied to provide a flow discharge area per unit length of the operative portion of the catheter which increases in the distal direction, and means to direct treatment fluid to the at least one additional lumen adapted to receive said fluid.

The presently preferred embodiment generally comprises an outer tubular member, an inner tubular member concentrically disposed within the outer tubular member and defining the additional lumen as an annular lumen therebetween which is adapted to direct therapeutic fluids to the distal portion of the catheter having flow passageways in the wall thereof. The inner tubular member has a central lumen extending therethrough which is adapted to receive a guidewire so that the catheter can be advanced thereover to a desired location within the patient's vascular system. The flow passageways are preferably provided in a distal portion of the catheter and may be linearly or spirally disposed along the length depending upon the flow pattern desired at the vascular site. While in the presently preferred embodiment, the transverse cross-sectional area of evenly spaced flow passageways is increased in the distal direction to control the flow thereof, alternate embodiments would include an increase in the number of holes per unit of length or a decrease in the distal direction to increase the area of the discharge or variations in spacing.

The passageways in the catheter wall are preferably formed by a laser beam which can accurately form very small holes in the outer tubular member of the vascular catheter. Such small holes allow for the use of very low internal pressure within the annular lumen between the inner and outer tubular member which can be easily controlled to result in very low volume jets of fluid through each of such passageways onto the treatment site.

These and other advantages of the invention will become more apparent from the following detailed description of the invention, including the exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a elevational view partially in section of a vascular catheter for therapeutic fluids which embodies features of the invention;

FIGURE 2 is a cross-sectional view taken along the lines of 2-2 shown in FIG. 1;

FIGURE 3 is a top view taken along the lines of 3-3 shown in FIG. 1 to illustrate the size and placement of flow passageways in the distal operative portion of the catheter and;

FIGURE 4 is an alternate embodiment of the present invention wherein multiple lumens are provided for delivery of treatment fluids.

DETAILED DESCRIPTION OF THE INVENTION

Reference is made to FIG. 1 which illustrates a vascular catheter assembly 10 which embodies features of the invention. In general the catheter assembly 10 includes an elongated tubular body 11 having an outer tubular member 12 and an inner tubular member 13 concentrically disposed within

the outer tubular member and defining an annular lumen 14 therebetween. The inner tubular member 13 is adapted to receive a guidewire 15 which facilitates the advancement of the catheter assembly 10 to place the operative distal portion 16 thereof at a desired site in the patient's vascular system. The outer tubular member 12 is provided with a plurality of flow passageways 17 in the operative portion 16 which are spaced along the length thereof. The transverse cross-sectional area, i.e., the discharge area, of the passageways 17 increases with each successive passageway in the distal direction. The embodiment shown in FIG. 1 provides for the uniform spacing between the centerline of the individual passageways 17.

The proximal end of catheter assembly 10 is provided with a two-arm adapter 20, having one arm 21 for introducing therapeutic fluids into the annular lumen 14 and another arm for directing guidewire 15 into the lumen 23 within the inner tubular member 13.

A flexible tip 24 is provided on the distal end of tubular body 11 to lessen the trauma caused by the introduction of the catheter into the patient's blood vessel. Preferably, the tip is formed of a softer, more resilient plastic material than either the inner or outer member. As shown in FIG. 1, the inner tubular member 13 preferably extends to the distal tip of the tubular body 11 and supports the flexible tip 24. The flexible tip 24 closes off and seals the distal end of the annular lumen 14.

To provide a uniform flow of therapeutic fluids along the operative distal portion of the catheter 10, the discharge area of the flow passageways 17 per unit length of the operative portion 16 of the catheter increases in the distal direction. The transverse cross-section of individual passageways can be increased in the distal direction or in the alternative the number and density of passageways can be increased distally in order to maintain a desired uniform flow pattern of therapeutic fluid from the annular lumen 14.

In a presently preferred embodiment, the passageways 17 are formed through the outer tubular member 12 by means of a laser beam, preferably with a rectangular transverse cross section. The flow passageway is formed in two steps, as shown in FIG. 3. In the first step, an initial rectangular passageway 30 is formed by the laser beam through wall 31 of the outer tubular member 12 having a constant longitudinal dimension a with respect to the catheter axis (e.g., typically about 40 to about 80 microns) and a varying transverse direction b (e.g., typically from about 10 to about 60 microns). The discharge area for each hole generally should be less than 0.02 mm^2, preferably about 0.001 to about 0.01 mm^2. The second step involves the formation of an overlapping rectangularly shaped passageway 32 shown in phantom generally parallel to and axially in line with the first passageway 30 having essentially the same dimensions to produce an elongated rectangularly shaped passageway 17. Typical overlap is about 10 microns, which provides a typical longitudinal dimension of the finished flow passageway of about 70 microns. The spacing between the individual flow passageways 17 is about 1 to about 8 cm, preferably about 1 to about 4 cm from centerline to centerline. The presently preferred total number of flow passageways, as illustrated in FIG. 1, is 8 on one side of the outer tubular member 13. However, a greater or lesser amount of passageways can be employed and they need not be linearly spaced along one side. In the presently preferred embodiments, the flow passageways are drilled with a Model 1100 XMR laser device with an energy density of about 14 joules/cm.

The catheter components can be formed from conventional materials. For example, the outer tubular member 12 may be formed from extruded polyethylene with an outside diameter of 0.068 inch (1.72 mm) and an inside diameter of 0.058 inch (1.47 mm). The inner member may be formed from extruded polypropylene with an outside diameter of about 0.04 inch (1.02 mm) and an inside diameter of about 0.03 inch (0.76 mm). The multi-arm adapter 20 is generally formed of conventional polyethylene materials.

FIG. 4 illustrates an alternate embodiment where the outer tubular member 12 and inner tubular member 13 are formed (e.g., extruded) into a unitary structure with struts or walls 26 extending between the inner and outer tubular members forming a plurality of separated lumens 33. Each of the lumens may be provided with one or more flow passageways 17 as previously described.

To effectively remove thrombus, very low flow races of about 0.1 to about 1.5 cm^3/hr have been found suitable. Such flow rates can be obtained with the present catheter assembly with internal fluid pressures of about 2 to about 5 psi (about 13,790 to about 34,475 Pa).

The catheter assembly 10 of the invention is utilized by first passing a guidewire 15 through a thrombus in a patient's artery which is to be treated. The catheter 10 of the invention is then advanced over the guidewire into the thrombus so that the operative portion 16 of the catheter extends through the thrombus. Thrombolytic fluid, e.g., containing urokinase, streptokinase, TPA, or the like, is then pumped by suitable means such as a syringe mounted on arm 21 of adapter 20 through the annular passageway 14 at about 1 cm^3/hr. The slow delivery rates allow deep penetration of the thrombolytic fluid into the thrombus for the effective break-up and dissolution thereof. After

the thrombus has been removed, the catheter 10 can then be removed over the guidewire 15. If an angioplasty is needed for atheroma underlying the thrombus, a conventional balloon dilatation catheter can then be advanced over the previously placed guidewire to the site of the atheroma for the dilation thereof.

While the present invention has been described herein in terms of certain preferred embodiments, various improvements can be made to the invention without departing from the scope thereof. For example, inflatable balloons can be provided on the distal and proximal ends of the operative portion of the catheter in order to occlude the patient's blood vessel, thereby holding the thrombolytic or other treatment fluid within the desired region of the patient's blood vessel. Other modifications can be made to the invention.

Claims

1. A multilumen catheter (10) for delivery of therapeutic fluid to a location within a patient's vascular system, comprising:
   a) an elongated tubular body (11) having a first lumen (23) with an axial opening in the distal end of the tubular body (11) which is adapted to receive a guidewire (15) and at least one additional lumen (14) which is adapted to receive therapeutic fluid;
   b) a plurality of longitudinally spaced fluid passageways (17) which extend through a sidewall of the elongated tubular body (11) from the at least one additional lumen (14) adapted to receive therapeutic fluid to the exterior of the tubular body (11), the transverse cross-sectional area of the passageways (17) and the spacing therebetween being varied to provide a flow discharge area per unit length of the operative portion (16) of the catheter which increases in the distal direction; and
   c) means (20) to direct treatment fluid to the at least one additional lumen (14) adapted to receive said fluid.

2. The catheter of claim 1 wherein the elongated tubular body (11) comprises an inner tubular member (13) having he first lumen (23) disposed longitudinally therein and an outer tubular member (12) disposed concentrically about the inner tubular member (13) and defining the additional lumen (14) as an annular lumen between the inner and outer tubular members (13, 12).

3. The catheter of claim 2 wherein the annular additional lumen (14) adapted to receive treatment fluid is broken up into separate parallel lumens (33) by walls (26) which extend between the inner and outer tubular members (13, 12).

4. The catheter of claim 1 wherein the flow passageways (17) through the wall of the tubular body (11) are equally spaced in the longitudinal direction.

5. The catheter of claim 1 wherein the flow passageways (17) have transverse cross-sectional areas less than 0.02 mm^2.

6. The catheter of claim 1 wherein the flow passageways (17) have transverse cross-sectional areas of about 0.001 to about 0.01 mm^2.

7. The catheter of claim 1 wherein the transverse cross-sectional shape of the flow passageways (17) is rectangular.

8. The catheter of claim 1 wherein the flow passageways (17) through the wall of the tubular body (11) are evenly spaced longitudinally therein.

Patentansprüche

1. Mehrlumenkatheter (10) zur Abgabe eines therapeutischen Fluids an eine Stelle im Gefäßsystem eines Patienten mit
   a) einem langgestreckten rohrförmigen Körper (11), der ein erstes Lumen (23) besitzt, das im distalen Ende des rohrförmigen Körpers (11) eine axiale Öffnung bildet und zur Aufnahme eines Führungsdrahtes (15) geeignet ist, und der mindestens ein zusätzliches Lumen (14) besitzt, das zur Aufnahme des therapeutischen Fluids geeignet ist;
   b) einer Mehrzahl von in Längsabständen voneinander angeordneten Fluidkanälen (17), die eine Seitenwand des langgestreckten rohrförmigen Körpers (11) von dem mindestens einen zusätzlichen Lumen (14) aus durchsetzen und zur Abgabe des therapeutischen Fluids an die Außenseite des rohrförmigen Körpers (11) geeignet sind, wobei die Querschnittsfläche der Kanäle (17) und die Abstände zwischen ihnen derart variieren, daß die Durchflußquerschnittsfläche pro Längeneinheit des wirksamen Teils (16) des Katheters in der distalen Richtung zunimmt, und
   c) einer Einrichtung (20) zur Abgabe von Behandlungsfluid an das mindestens eine zusätzliche Lumen (14), das zur Aufnahme dieses Fluids geeignet ist.

2. Katheter nach Anspruch 1, in dem der langgestreckte rohrförmige Körper (11) ein inneres rohrförmiges Glied (13) aufweist, in dem sich das erste Lumen (23) in der Längsrichtung erstreckt, und ein äußeres rohrförmiges Glied (12), das das innere rohrförmige Glied (13) konzentrisch umgibt und das zusätzliche Lumen (14) als Ringlumen zwischen dem inneren und dem äußeren rohrförmigen Glied (13, 12) begrenzt.

3. Katheter nach Anspruch 2, in den das zur Aufnahme des Behandlungslfuids geeignete, ringförmige zusätzliche Lumen (14) durch Wände (26), die sich zwischen dem inneren und dem äußeren rohrförmigen Glied (13, 12) erstrecken, in voneinander getrennte, parallele Lumen (33) unterteilt ist.

4. Katheter nach Anspruch 1, in dem die die Wand des rohrförmigen Körpers (11) durchsetzenden Strömungskanäle (17) in gleichen Längsabständen voneinander angeordnet sind.

5. Katheter nach Anspruch 1, in dem die Querschnittsflächen der Strömungskanäle (17) kleiner sind als 0,02 mm^2.

6. Katheter nach Anspruch 1, in dem die Querschnittsflächen der Strömungskanäle (17) kleiner sind als 0,01 mm^2.

7. Katheter nach Anspruch 1, in dem die Strömungskanäle (17) eine rechteckige Querschnittsform haben.

8. Katheter nach Anspruch 1, in dem die die Wand des rohrförmigen Körpers (11) durchsetzenden Strömungskanäle (17) über dessen Länge gleichmäßig verteilt sind.

Revendications

1. Cathéter à lumières multiples (10) destiné à l'apport d'un fluide thérapeutique à un site à l'intérieur de l'appareil vasculaire d'un malade, comprenant :
   a) un corps tubulaire allongé (11) présentant une première lumière (23) dotée d'une ouverture axiale dans l'extrémité distale du corps tubulaire (11), conçue pour loger un fil de guidage (15) et au moins une lumière additionnelle (14) conçue pour loger un fluide thérapeutique;
   b) une pluralité de passages de fluide (17) espacés longitudinalement, qui s'étendent à travers une paroi latérale du corps tubulaire allongé (11) de la lumière additionnelle (14), au nombre minimal de 1, conçue pour loger le fluide thérapeutique, à l'extérieur du corps tubulaire (11), l'aie de la section transversale des passages (17) et leur espacement étant diversifiés pour fournir une aire de décharge d'écoulement par unité de longueur de la partie opérationnelle (16) du cathéter augmentant dans la direction distale ; et
   c) un moyen (20) permettant de diriger le fluide thérapeutique vers la lumière additionnelle (14), au nombre minimal de 1, conçue pour loger ledit fluide.

2. Cathéter selon la revendication 1, dans lequel le corps tubulaire allongé (11) comprend un élément tubulaire interne (13) contenant la première lumière (23) disposée longitudinalement et un élément tubulaire externe (12) disposé concentriquement autour de l'élément tubulaire interne (13) et définissant la lumière additionnelle (14) en tant que lumière annulaire entre les éléments tubulaires interne et externe (13, 12).

3. Cathéter selon la revendication 2, dans lequel la lumière additionnelle annulaire (14) conçue pour loger le fluide thérapeutique est divisée en lumières (33) parallèles distinctes par des parois (26) qui s'étendent entre les éléments tubulaires interne et externe (13, 12).

4. Cathéter selon la revendication 1, dans lequel les passages d'écoulement (17) à travers la paroi du corps tubulaire (11) sont espacés régulièrement dans la direction longitudinale.

5. Cathéter selon la revendication 1, dans lequel les passages d'écoulement (17) présentent des aires de section transversale inférieures à 0,02 mm^2.

6. Cathéter selon la revendication 1, dans lequel les passages d'écoulement (17) présentent des aires de section transversale comprises entre environ 0,001 et environ 0,01 mm^2.

7. Cathéter selon la revendication 1, dans lequel la forme de la section transversale des passages d'écoulement (17) est rectangulaire.

8. Cathéter selon la revendication 1, dans lequel les passages d'écoulement (17) à travers la paroi du corps tubulaire (11) sont espacés régulièrement dans ce dernier dans le sens longitudinal.

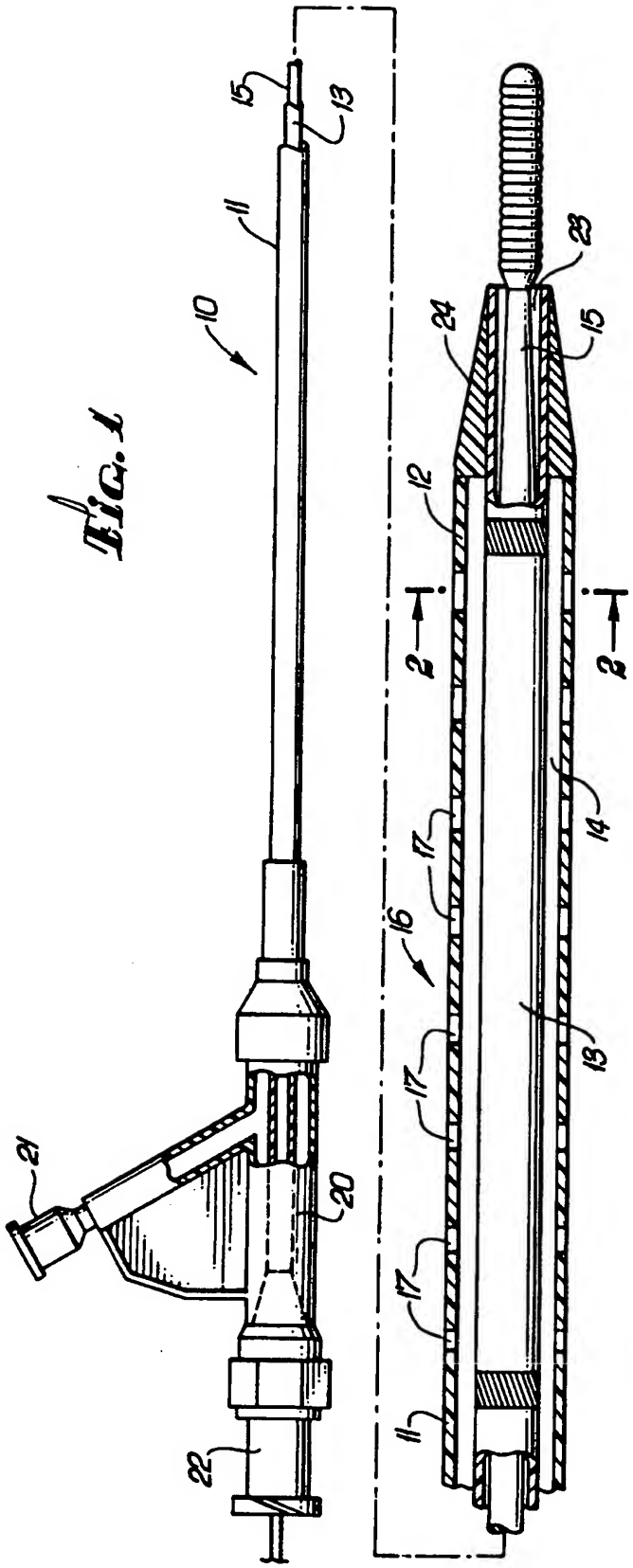

Fig. 1

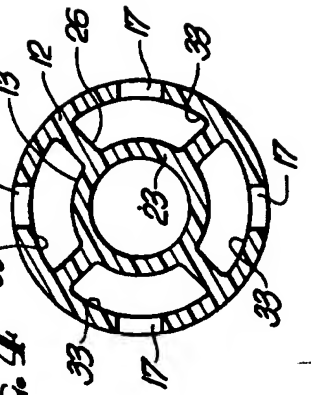

Fig. 4

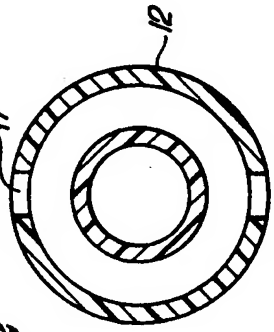

Fig. 2

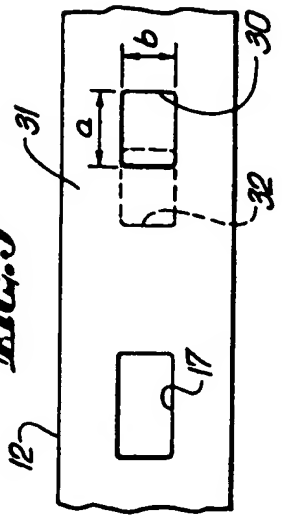

Fig. 3